REMARKS

In the last Office Action, claims 28-42 were rejected under 35 U.S.C. §103(a) as being unpatentable over US 5,337,733 to Bauerfeind et al. ("Bauerfeind") in view of US 4,406,656 to Hattler et al. ("Hattler"), and claim 42 was further rejected under 35 U.S.C. §103(a) as being unpatentable over Bauerfeind in view of Hattler and further in view of US 5,279,596 to Castaneda et al. ("Castaneda").

In accordance with this response, independent claim 28 has been amended in a minor respect and dependent claim 40 has been amended to correct an obvious error. Applicant respectfully requests reconsideration of his application and withdrawal of the prior art rejections.

The present invention relates to a guide device for positioning a catheter in a body duct. In the embodiment of the invention illustrated in Fig. 1 and embodied in the claims, the guide device comprises a flexible sleeve 13 dimensioned to be inserted into a body duct, and a first elongate, stretchable hollow body 2 disposed inside the sleeve 13 and extending in an axial direction along the central part of the sleeve. A plurality of second elongated bodies 3 are disposed inside the sleeve 13 around the outer circumference of the first body 2, and the second bodies 3 extend lengthwise in the axial direction in side-by-side relation with one another along the sleeve 13. The first and second bodies 2,3 are movable relative to one another

to impart flexibility to the guide device to facilitate insertion into a body duct. After insertion, stiffness is imparted to the guide device by, for example, a pressurized fluid inside the first hollow body 2, which stretches the first body radially outwardly to radially press the second bodies 3 against the inner wall of the sleeve 13, thereby imparting stiffness to the guide device.

Applicant respectfully traverses the prior art rejection of claims 28-42 as being unpatentable over Bauerfeind in view of Hattler.

Independent claim 28 recites a guide device comprising a flexible sleeve, a first elongate, stretchable hollow body disposed inside the sleeve and extending lengthwise in an axial direction along the central part of the sleeve, and plural second elongate bodies disposed inside the sleeve around the outer circumference of the first body extending lengthwise in the axial direction in side-by-side relation with one another along the sleeve. Claim 28 further recites that the first and second bodies are movable relative to one another to impart flexibility to the guide device, and means for stretching the first body radially outwardly to radially press the second bodies against the inner wall of the sleeve to impart stiffness to the guide device. No similar guide device is disclosed or suggested by the combination of Bauerfeind and Hattler.

The principal reference to Bauerfeind discloses a tubular inserting device with variable rigidity for inserting a fiberoptic instrument, such as a colonoscope, into a patient's colon. In the embodiment illustrated in Figs. 1-2, which was applied in the statement of rejection, the device comprises a tubular outer wall (flexible sleeve) 18 in which is disposed a tubular inner wall (first stretchable body) 16. The inner and outer walls 16,18 are spaced apart from one another by an annular space 20. The inner wall 16 is made thinner and more flexible than the outer wall 18 (column 5, lines 36-42). A series of support elements 32 are disposed evenly distributed on the outside of the inner wall 16, and a series of support elements 36 are arranged on the inside of the outer wall 18 in staggered relation with respect to the support elements 32. A colonoscope 50 (not illustrated in Fig. 2) is slidably inserted into the tubular inner wall 16 for insertion by the device into a patient's colon.

In use, pressurized air is introduced into the annular space 20 to press the inner wall 16 inwardly into engagement with the colonoscope whereby the inserting device is as flexible as the colonoscope. On the other hand, when the annular space 20 is evacuated and negative pressure prevails in the space 20, the tubular inner wall is expanded radially outwardly so that the support elements 32 on the inner wall engage with the support elements 36 on the outer wall to stiffen or rigidify the device.

In Bauerfeind, the tubular inner wall (first stretchable body) 16 is not disposed along the central part of the sleeve (tubular outer wall) 18, as required by claim 28, but rather is disposed remote from the central part of the sleeve in close proximity to the inner periphery of the sleeve. In the reference, the colonoscope or other fiberoptic instrument -- not the inner tubular wall 16 -- extends along the central part of the sleeve 18, and it would not be possible to reduce the size of the tubular inner wall 16 so that it extends along the central part of the sleeve 18 as such would preclude insertion of the colonoscope or other fiberoptic instrument into the tubular inner wall. Thus even if Bauerfeind were modified in view of Hattler as proposed in the statement of rejection, the modified device would not resemble the guide device recited in claim 28.

According to the rejection, the Examiner contends that it would have been obvious to one of ordinary skill in the art to modify the Bauerfeind device to make the support elements (second bodies) 32 as separate bodies disposed around and movable relative to the sleeve (first body) 18 as taught by Hattler in order to impart stiffness to the guide device. Applicant vigorously disagrees. Firstly, as disclosed by Bauerfeind, the inner wall 16, including the support elements 32, is formed of a tubular film of pliable plastic material and, as illustrated in Fig. 2, is of one-piece construction. If the support elements 32 were separately formed and loosely disposed in the annular space

20 so as to be movable relative to the inner wall 16 as proposed in the rejection, the support elements 32 would no longer be maintained in alignment with the gaps 38 between adjacent ones of the support elements 36 on the outer wall 18 and consequently, the device would no longer operate as intended. For example, if one or more of the separately formed support elements 32 were radially aligned with one or more of the support elements 36, such would prevent outward expansion of the inner wall 16 when vacuum is applied to the annular space 20. Thus one of ordinary skill in the art would not have found it obvious to form the support elements 32 as separate elements that are movable relative to the inner wall 16, as proposed in the statement of rejection.

Secondly, Hattler would not have led one of ordinary skill in the art to modify the Bauerfeind device to form the support elements 32 separate from the inner wall 16 and movable relative to the inner wall 16. Unlike Bauerfeind, Hattler relates to a venous catheter having collapsible multi-lumens for carrying multiple fluids into and out from the vein of a patient using a single catheter. In the embodiment shown in Figs. 8-9, which was applied in the rejection, the catheter comprises a central guide 800 formed of solid, stiff material surrounded by a plurality of collapsible lumens 820 which are encased in an expandable sheath 830. As shown in Fig. 9, during use, fluid 900 flows through one of the collapsible lumens 820 and expands both

the lumen and the sheath 830 whereby the lumen is expanded to normal size to handle a normal flow capacity. It is not understood in what manner the Bauerfeind device would be modified in view of Hattler to arrive at the claimed invention.

In Bauerfeind, the support elements 32 are solid plastic elements molded in one piece with the inner wall 16 and are provided to stiffen the device when vacuum is applied to the annular space 20 without expanding the sleeve 18. By contrast, in Hattler the collapsible lumens 820 are separate hollow elements that are expanded by pressurized fluid flowing therethrough to expand the flexible sheath 830 so that the lumen is expanded to a size to handle normal flow capacity. The purpose, function and construction of the collapsible lumens 820 are completely different from than those of the solid support elements 32 of Bauerfeind, and one of ordinary skill in the art would not have been led by any teaching or suggestion in either reference to modify the Bauerfeind device in the manner proposed in the rejection.

Applicant respectfully submits that the Examiner has failed to establish a prima facie case of obviousness of the subject matter of claim 28 based on the combined teachings of Bauerfeind and Hattler. The manner in which the Bauerfeind inserting device is being modified in view of the Hattler collapsible multi-lumen catheter is unclear from the statement of rejection, and the proposed combination of references does not meet the criteria for establishing a prima facie case of obviousness within the meaning of 35 U.S.C. §103, which requires

some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine their teachings. See, e.g., Symbol Technologies, Inc. v. Opticon, Inc., 19 USPQ2d 1241, 1246 (Fed. Cir. 1991).

As set forth above, the references themselves lack any motivation to combine their teachings in a manner that would yield the claimed guide device. The only basis for the combination urged by the Examiner in the rejection is applicant's own disclosure, and such hindsighted rejections are improper. See, Diversitech Corp. v. Century Steps, Inc., 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Panduit Corp. v. Dennison Manufacturing Co., 227 USPQ 337, 343 (Fed. Cir. 1985); Interconnect Planning Corp. v. Feil, 227 USPQ 543, 551 (Fed. Cir. 1985).

The subject matter of many of the dependent claims is likewise not disclosed in the references thereby rendering these claims separately patentable. For example, claim 29 recites that the means for stretching the first body comprises a pressurized fluid inside the first body. In Bauerfeind, the first body (inner wall 16) is stretched by vacuum, not pressurized fluid.

Claim 30 requires that the second bodies undergo elastic deformation when pressed against the inner wall of the sleeve. In Hattler, the collapsible lumens 820 elastically deform the sleeve (sheath 830) rather than being deformed themselves by pressing against the sleeve.

Claim 31 requires that the second bodies become flattened between the inner wall of the sleeve and the outer circumference of the first body when the first body is stretched radially outwardly. By contrast, in Hattler the second bodies (lumens 820) are expanded into circular shape by fluid flowing therethrough as shown in Fig. 9.

Similar recitations appear in other dependent claims, none of which is disclosed in Bauerfeind or Hattler.

The reference to Castaneda has been cited for its teaching of a helical wire support in a tubular member to reduce kinks in the tubular member. However, Castaneda does not cure the deficiencies of Bauerfeind and Hattler with respect to claims 28-41 which, as noted above, patentably distinguish over these references.

In view of the foregoing, the application is now believed to be in allowable form. Accordingly, favorable reconsideration and passage of the application to issue are respectfully requested.

Respectfully submitted,

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OCTOBER 19, 2009
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